



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94364d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER
NWE-03-04W

VIA FEDERAL EXPRESS

October 15, 2003

Michael A. Trazzera
President and CEO
Sea Gold Seafood Products, Inc.
110 East Faunce Landing Road
Absecom, NJ 08201

Dear Mr. Trazerra:

We inspected your seafood processing facility, Sea Gold Seafood Products, Inc., located at 48 Antonio Costa Boulevard, New Bedford, MA on September 10 and 15, 2003. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6 (g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood products (ready-to-eat seafood salads and dips) are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviations observed were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for the variety of refrigerated, ready-to-eat seafood products you manufacture.

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records that are required for the processing of your ready-to-eat seafood salads and dips.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We acknowledge the receipt of your letter dated September 25, 2003 from Ms. Wendy Harwood outlining the steps you plan to take to correct the observed deviations. However, we still require your HACCP plan in order to fully evaluate your corrections. Per your letter, we look forward to receiving your HACCP plan on or before November 28, 2003.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail T. Costello
District Director
New England District Office

Cc: Wendy Harwood
Sea Gold Seafood Products, Inc.
48 Antonio Costa Boulevard
New Bedford, MA 02741